DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 30 2004

6161 '04 FEB -5 A9:53

David M. Fox
Hogan & Hartson
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: Docket No. 2003P-0321/CP1

Dear Mr. Fox:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on July 16, 2003, on behalf of ICN Pharmaceuticals, Inc. and Ribapharm, Inc. Your petition requests that the Agency refrain from approving abbreviated new drug applications (ANDAs) for ribavirin products with labeling that omits information about the product's use in combination with PEG-Intron (peginterferon alfa-2b).

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2003P-0321

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